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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN; the DISTRICT OF COLUMBIA; the CITY OF CHICAGO, and the CITY OF NEW YORK, *ex rel.* OSWALD BILOTTA,
Plaintiffs and Relator,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
Defendant.

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THE STATE OF NEW YORK,
Plaintiff,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
Defendant.

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ECF Case
Case No. 11 Civ 0071 (PGG)

COMPLAINT IN INTERVENTION OF THE STATE OF NEW YORK

JURY TRIAL DEMANDED

For its Complaint in Intervention against Defendant Novartis Pharmaceuticals Corporation ("Novartis"), the State of New York, by its attorney Eric T. Schneiderman, Attorney General for the State of New York, alleges as follows upon information and belief:

I. NATURE OF THE ACTION

1. The State of New York (the "State") brings this action to recover treble damages and civil penalties under the New York State False Claims Act, N.Y. State Finance Law §§ 187-190, and to recover damages and other monetary relief under N.Y. Social Services Law § 145-b, N.Y. Executive Law § 63(12), N.Y. Executive Law § 63-c, and unjust enrichment.

2. In particular, the State seeks to recover for damages incurred by the State as a result of Novartis's payment of kickbacks to physicians to induce them to prescribe certain prescription medications that were reimbursed by the New York State Medicaid program (the "Medicaid Program" or "Medicaid") and other State healthcare programs.

3. As set forth more fully below, from January 2002 through at least November 2011, Novartis systematically paid doctors to speak about certain of its drugs, including its cardiovascular drugs Lotrel and Valturna and its diabetes drug Starlix, at sham events that were often nothing more than a pretext for Novartis to wine and dine physicians at expensive venues where they could socialize with one another. Novartis's payments to the doctors, as well as the dinners and entertainment, were kickbacks to the speakers and the attendees to induce them to write prescriptions for Novartis drugs, in violation of New York State Medicaid regulations, 18 N.Y.C.R.R. §§ 504.6(d), 515.2, and 515.5; the New York State Anti-Kickback Statute, New York Social Services Law § 366-d(2)(b); and the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b.

4. According to Novartis's policies, speaker programs purportedly are events at which a doctor is paid to educate other doctors and health care professionals regarding the therapeutic effect of Novartis' drugs by presenting slides prepared by the company. In practice, Novartis held thousands of sham speaker programs in New York State and all over the country at which few or no slides were shown and the doctors who participated spent little or no time discussing the drug at issue. Instead, Novartis simply wined and dined the doctors at high-end restaurants with astronomical costs, as well as at other venues not conducive to an educational program. In connection with these speaker programs, Novartis also paid the doctors additional money to attend training events on the drugs, notwithstanding that the doctors ultimately spent little or no time discussing the drugs.

5. Novartis was well aware that its speaker programs created opportunities to provide kickbacks to doctors. In September 2010, Novartis entered into a settlement (the "September 2010 Settlement") with the U.S. Department of Justice, the State of New York, and other states to settle False Claims Act lawsuits based in part on false claims arising from illegal remuneration Novartis had paid to doctors through such mechanisms as speaker programs. The company signed a Corporate Integrity Agreement ("CIA") with the U.S. Department of Health and Human Services Office of Inspector General agreeing to implement a rigorous compliance program.

6. Yet even after entering into the CIA, Novartis's compliance program was inadequate to prevent illegal payments and other perquisites to doctors in conjunction with Novartis's speaker programs. Novartis did not adequately review its speaker programs to determine whether the programs were being used for an illegitimate purpose. The physician speaker programs were organized and conducted by Novartis's sales force, who were

compensated in part based upon the number of prescriptions for Novartis drugs written by the physicians. Furthermore, although many instances of speaker program abuse were reported to Novartis's compliance department, sanctions for illegal conduct were generally mere slaps on the wrist. In some cases, sales representatives who violated Novartis's own speaker program policies were nevertheless promoted. Even after September 2010, Novartis continued to conduct bogus speaker programs that were simply vehicles for paying kickbacks to doctors in the form of honoraria and expensive meals.

7. By paying kickbacks to doctors, Novartis caused the submission of thousands of false claims for payment to the New York State Medicaid Program. Accordingly, Novartis is liable under the New York False Claims Act for treble damages and penalties for these claims for reimbursement for Lotrel, Valturna and Starlix, as well as for other Novartis cardiovascular drugs, as discussed in detail below.

II. JURISDICTION AND VENUE

8. Eric T. Schneiderman is the Attorney General of the State of New York. He is authorized to recover three times the amount of damages sustained by the State on account of defendant's false and fraudulent claims and statements along with civil penalties of between $6,000 and $12,000 per violation pursuant to the New York State False Claims Act, N.Y. State Fin. Law §§ 189, 190(1), to recover treble damages for overpayments of public funds obtained by means of false statements or other fraudulent schemes, N.Y. Social Services Law § 145-b(2), to prosecute and institute all actions and proceedings in which the State is interested, N.Y. Executive Law § 63(1), and to seek restitution for repeated or persistent fraudulent or illegal business acts or practices, N.Y. Executive Law § 63(12).

9. Relator Oswald Bilotta filed a complaint on behalf of himself, the Federal government, the State of New York, and numerous other State and local entities alleging violations of Federal and State False Claims Acts.

10. On July 17, 2013, the State of New York filed a Notice of Intention to Intervene in this action in part, and to file a Complaint in Intervention pursuant to N.Y. State Fin. Law § § 190(2)(c)(i) and 190(2)(d). On July 25, 2013, the Court entered an Order granting the State of New York 30 days from the date of the Order to file its Complaint in Intervention.

11. This Court has subject matter jurisdiction to entertain the original actions under 28 U.S.C. §§ 1331 and 1345, and pursuant to 31 U.S.C. § 3732(b) because the action arises from the same transaction or occurrence as an action brought under 31 U.S.C. § 3730, and it has supplemental jurisdiction to entertain the state statutory, common and equitable causes of action pursuant to 28 U.S.C. § 1367(a).

12. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S. C. §§ 1391(b) and 139l(c), because Novartis does business in this district and some of the false or fraudulent acts occurred in this District.

III. PARTIES

13. Plaintiff State of New York was at all times relevant to this action a sovereign state of the United States of America.

14. Relator Oswald Bilotta, a former resident of New York who moved to North Carolina in July 2012, is a former employee of Novartis.

15. Defendant Novartis is a subsidiary of Novartis AG, an international pharmaceutical company headquartered in Basel, Switzerland. Novartis, which is headquartered

in East Hanover, New Jersey, does business throughout the United States, including in the Southern District of New York.

IV. THE LAW

A. The New York False Claims Act

16. The New York False Claims Act provides, in pertinent part, that any person who:

> a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
> b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> c) conspires to commit a violation of [paragraphs (a) or (b)] of this subdivision;
> * * *
> shall be liable to the state or a local government, as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of that person.
> N.Y. State Fin. Law § 189(1).

17. "Knowing and knowingly" means that with, respect to information, a person:

> (i) has actual knowledge of the information;
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
> (iii) acts in reckless disregard of the truth or falsity of the information.
> N.Y. State Fin. Law § 188(3).

18. Under the New York False Claims Act, a "claim":

> (a) means any request or demand, whether under a contract or otherwise, for money or property that:
> (i) is presented to an officer, employee or agent of the state or a local government; or
> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the state or a local government's behalf or to advance a state or local government program or interest, and if the state or local government (A) provides or has provided any portion of the money or property requested or demanded; or (B) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

N.Y. State Fin. Law § 188(1).

B. N.Y. Social Services Law § 145-b

19. N.Y. Social Services Law § 145-b(1)(a) provides, in pertinent part, that:

> It shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished pursuant to this chapter.

20. "Statement or representation," as used within Social Services Law 145-b(1)(a) includes, but is not limited to: a claim for payment made to the state, a political subdivision of the state, or an entity performing services under contract to the state or a political subdivision of the state; an acknowledgment, certification, claim, ratification or report of data which serves as the basis for a claim or a rate of payment, financial information whether in a cost report or otherwise, health care services available or rendered, and the qualifications of a person that is or has rendered health care services. N.Y. Social Services Law § 145-b(1)(b).

21. For violations of Social Services Law §145-b(1), the State is entitled to recover treble damages, penalties, and costs. N.Y. Social Services Law § 145-b(2).

C. N.Y. Executive Law § 63(12)

22. New York Executive Law § 63(12) provides, in pertinent part, that:

> Whenever any person shall engage in repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business, the attorney general may apply . . . for an order enjoining the continuance of such business activity or of any fraudulent or illegal acts, directing restitution and damages . . . .

D. N.Y. Executive Law § 63-c

23. New York Executive Law § 63-c(1) provides, in relevant part, that:

> Where any money, funds, credits, or other property, held or owned by the state, or held or owned officially or otherwise for or in behalf of a governmental or other public interest, . . . has heretofore been . . . without right obtained . . . an action to recover the same, or to recover damages or other compensation for so obtaining . . . of the same, or both, may be maintained by the state in any court of the state, or before any court or tribunal of the United States, or of any other state, or of any territory of the United States, or of any foreign country, having jurisdiction. . . .

E. The Medicaid Program – Federal Participation

24. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. The federal involvement in Medicaid is to provide matching federal funds and to ensure that states comply with minimum standards in the administration of the program.

25. The federal Medicaid statute sets the minimum requirements for state Medicaid programs to qualify for federal funding, which is called federal financial participation. 42 U.S.C. § 1396, et seq.

26. At all times relevant hereto, the United States has provided funds to New York for its Medicaid program, which New York administers through the New York State Department of Health. New York State pays health care providers, including pharmacies and physicians, according to established rates, and the federal government then pays a statutorily established share of "the total amount expended . . . as medical assistance under the State plan." See 42 U.S.C. §§ 1396b(a)(l).

27. New York State's Medicaid program is required to have a fraud detection program, and a state plan that provides for exclusion of persons who have committed fraud. Cf. 42 C.F.R. § 455.

F. New York State Medicaid Regulations

28. New York's Medicaid program covers prescription medications. 18 N.Y.C.R.R. § 505.3. For most prescription medications, including those medications relevant to this Complaint, medications are dispensed to Medicaid recipients by pharmacies pursuant to a prescription written by a physician or other licensed healthcare professional authorized to prescribe medications in New York State. Pharmacies submit claims to Medicaid and are reimbursed for the prescription medications according to a formula set by law. See EMedNY New York State Pharmacy Manual Policy Guidelines, Version 2011-1, at p. 26.[1]

29. Pursuant to 18 NYCRR § 504.1, "Any person who furnishes medical care, services or supplies for which payments under the [Medicaid] program are to be claimed; or who arranges the furnishing of such care, services or supplies; or who submits claims for or on behalf of any person furnishing or arranging for the furnishing of such care, services or supplies must enroll as a provider of services prior to being eligible to receive such payments, to arrange for such care, services or supplies or to submit claims for such care or supplies." 18 NYCRR § 504.1(b)(1).

30. Before submitting claims for payment to the New York State Medicaid program, whether in paper or electronic form, providers, including physicians and pharmacies, are required to first sign a Certification Statement for Provider Billing Medicaid (hereinafter, "Certification Statement"). See EMedNY New York State Medicaid General Billing Guidelines-Professional, Version 2013-01, at p. 5; New York State EMedNY Billing Guidelines-Pharmacy, Version 2013-01 at p. 5. In the Certification Statement, the provider certifies that, for all claims submitted to Medicaid, "I (or the entity) have furnished or caused to be furnished the care,

[1] EMedNY Provider Manuals are available at www.emedny.org

services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations."

31. Accordingly, providers must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations.

32. A provider must renew her Certification Statement periodically by signing a new Certification Statement. The Certification Statement last signed by the provider remains in effect for all claims until a new Certification Statement is signed by the provider.

33. Since in or about 2007, the Certification Statement has applied to all claims submitted to Medicaid, whether submitted electronically or on paper. Prior to 2007, for paper claims the provider's certification statement was included on the paper claim form submitted to Medicaid, and the provider certified that the care, services or supplies listed on the claim form were "furnished in accordance with applicable Federal and State laws and regulations" when submitting the claim form for payment.

34. 18 N.Y.C.R.R. § 515.2(b) specifically prohibits as an "unacceptable practice":

> (5) Bribes and Kickbacks . . .
> (ii) soliciting or receiving either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the [Medicaid] program;
>
> * * *
>
> (iv) offering or paying either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the [Medicaid] program
>
> * * *

35. 18 N.Y.C.R.R. § 515.2(a) also specifically prohibits as an "unacceptable practice" conduct that is contrary to:

> (3) the official rules and regulations of the Departments of Health, Education and Mental Hygiene, including the latter department's offices and division, relating to standards for medical care and services under the [Medicaid] program; or
>
> (4) the regulations of the Federal Department of Health and Human Services promulgated under title XIX of the Federal Social Security Act.

36. Pursuant to 18 N.Y.C.R.R. § 518.1(c) "overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake."

37. Title 18 provides further that "[n]o payments will be made to or on behalf of any person for the medical care, services or supplies furnished . . . in violation of any condition of participation in the program," nor will payments be made for "for any medical care, services or supplies ordered or prescribed in violation of any condition of participation in the program." 18 N.Y.C.R.R. § 515.5(a), (b). Accordingly, all claims for payment to Medicaid resulting from kickbacks are in violation of a material condition of payment of the New York State Medicaid Program.

G. The Federal Anti-Kickback Statute

38. The federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that payoffs to those who can influence healthcare decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or harmful to a vulnerable patient population. To protect the integrity of the program from these harms, which are difficult to detect, Congress enacted a per se prohibition against the payment of

kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. See Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

39. The Federal Anti-Kickback Statute ("AKS") prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical services, including services provided under the Medicaid program. In pertinent part, the statute states:

> (b) Illegal remuneration
> (1) whoever knowingly and willfully solicits or receives any remuneration (including and kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind –
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or part under a Federal health care program, . . .
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person --
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or part under a Federal health care program, . . .
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

40. Violation of the statute can also subject the perpetrator to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of $50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

41. As codified in the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, codified at 42 U.S.C. § 1320a-7b(g), "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the Federal False Claims Act]."

42. According to the legislative history of the PPACA, this amendment to the AKS was intended to clarify "that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854.

43. Compliance with the AKS, 42 U.S.C. § 1320a-7b(b), is a condition of payment under federally funded healthcare programs.

H. The New York State Anti-Kickback Statute

44. The New York State Anti-Kickback Statute provides, in pertinent part, that:

No medical assistance provider shall:

> (a) solicit, receive, accept or agree to receive or accept any payment or other consideration in any form from another person to the extent such payment or other consideration is given: (i) for the referral of services for which payment is made . . . ; or . . . (ii) to purchase, lease or order any good, facility, service or item for which payment is made . . . ; or

> (b) offer, agree to give or give any payment or other consideration in any form to another person to the extent such payment or other consideration is given: (I) for the referral of services for which payment is made . . . ; or . . . (ii) to purchase, lease or order any good, facility, service or item for which payment is made . . .
>
> New York Social Services Law § 366-d(2).

45. Violation of the New York Anti-Kickback Statute can subject the perpetrator to criminal prosecution, fines of between $500 and $10,000, and, if the perpetrator has obtained money or property through the violation, a fine not to exceed double the amount of the gain from the violation. Id. § 366-d(3)(c).

V. FACTUAL ALLEGATIONS

A. Novartis Was Well Aware that Speaker Programs Without Sufficient Controls Could Violate Federal and State Anti-Kickback Statutes

46. Novartis recognized the need to comply with Federal and State Anti-Kickback Statutes in promoting its drugs to health care professionals. Novartis's Ethics and Compliance ("E&C") Policies, originally issued in 2003 and reissued in January 2006 and in subsequent years, provide that:

> The Federal Anti-kickback Statute makes it illegal to knowingly and willfully provide any "remuneration" in return for:
>
> (1) referring a person to another person for items or services covered under federal health care programs; or
> (2) purchasing or recommending the purchase of any good or service which is paid for by federal health care programs.
>
> "Remuneration" is defined very broadly and includes any item of value which is provided with the intent to induce the actions described above. Essentially, this law, and similar state statutes, prohibits bribes and kickbacks. The federal statute applies to payments made under virtually any federal healthcare program - not just Medicare and Medicaid. Note again that many state statutes similarly prohibit such activities.
>
> Under the Anti-kickback Statute, it is illegal to solicit (ask for) or receive kickbacks, as well as to offer to pay a kickback. Any of these actions constitutes a felony and is

> punishable by a fine up to $25,000 per violation and imprisonment up to five years, or both. In addition, the government may impose civil fines and may terminate an entity's right to provide products and services to patients whose care is paid for by government programs.

47. Novartis's E&C Policies also acknowledge that "[j]udicial and administrative interpretations of this law have been very broad" and that "[t]he statute is violated if even one purpose (as opposed to a primary or sole purpose) is to induce the Healthcare Provider to prescribe its product." Novartis's E&C Policies also note that the "government will infer" that a pharmaceutical company has an intent to induce a healthcare provider to prescribe its product when a payment or other benefit to a provider for a purported service "lacks substance."

48. Novartis's E&C Policies also recognize that "relationships with Healthcare Professionals are intended to benefit patients and to enhance the practice of medicine." The policies state that "[i]nteractions with Healthcare Professionals should be focused on providing information about our products, providing scientific and educational information and supporting medical research and education in venues that are conducive to such discussions." They further note that inviting health care professionals to events such as fishing trips "is inappropriate and is not permitted."

49. This language in Novartis's E&C Policies parallels language in the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals ("the PhRMA Code") issued in 2004 and reissued in 2009. Novartis, along with other major pharmaceutical companies, is a member of PhRMA, a signatory to the Code and has announced its intention to abide by the Code. In addition, Novartis has expressly certified that it is in compliance with the Code. The PhRMA Code provides that "[i]nteractions" between pharmaceutical company employees and health care professionals "should be focused on

informing healthcare professionals about products, providing scientific and educational information, and supporting medical education."

50. In addition to setting forth general rules, Novartis's E&C Policies also contain rules specific to speaker programs. Starting in 2003 and continuing through the present, Novartis's E&C Policies have provided that speaker programs must be held at venues that are "conducive to an exchange of medical information." As of 2006, Novartis's E&C Policies have also provided that "[f]ood and beverages are intended to be ancillary to meaningful discussion," must be in "modest amounts (quantity and cost)," and must be "incidental to a professional discussion or interaction." (Emphasis in original).

51. These policies parallel the PhRMA Code, which states that:

> In connection with [speaker programs and other promotional events], it is appropriate for occasional meals to be offered as a business courtesy to the healthcare professionals as well as members of their staff attending presentations, so long as the presentations provide scientific or educational value and the meals (a) are modest as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication.

52. In addition, the PhRMA Code provides that "[c]ompanies should continue to ensure that speaking arrangements are neither inducements nor rewards for prescribing a particular medicine or course of treatment." Further, it provides that "companies should not provide any entertainment or recreational items, such as . . . vacation trips, to any healthcare professional who is not a salaried employee of the company."

53. In further recognition that speaker programs must have a legitimate purpose to comply with the Federal and State Anti-Kickback Statutes, at all times relevant to the complaint, since 2003 and continuing through the present, Novartis's E&C Policies have also required that speakers make a presentation using a slide deck provided to them by Novartis. In addition,

Novartis's E&C Policies provide that programs must have at least three health care professionals in attendance and that at least one Novartis sales representative must be present at every speaker program. Since at least 2008, Novartis's E&C Policies have also provided that doctors or other practitioners from the speaker's own practice cannot be included in determining whether a program has at least the minimum three attendees.

B. In September 2010, Novartis Entered into a Settlement With the Federal Government and the States for Speaker Program Fraud, Among Other Unlawful Activity, and Novartis Became Subject to a Corporate Integrity Agreement

54. On September 27, 2010, Novartis settled FCA claims with the federal government, the State of New York, and other States, based in part on Federal and State Anti-Kickback Statute violations. The September 2010 Settlement stated that Novartis had "provided illegal remuneration, through mechanisms such as speaker programs, advisory boards, and gifts (including entertainment, travel and meals), to health care professionals to induce them to promote and prescribe the drugs Diovan, Zelnorm, Sandostatin, Exforge, and Tekturna, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b)."

55. At the same time as the settlement, Novartis also entered into a CIA with the Office of Inspector General of the Department of Health and Human Services. The CIA requires Novartis, among other things, to "ensure that [its] Policies and Procedures address . . . appropriate ways to conduct Promotional Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the federal anti-kickback statute . . . and the False Claims Act . . . ." CIA at Section III(B)(3)(c). The CIA also provides that Novartis's compliance policies and procedures must "address . . . programs to educate sales representatives, including but not limited to presentations by [health care professionals] . . . ."

and "be designed to ensure that the programs are used for legitimate and lawful purposes . . . ." *Id.* at (3)(1).

56. The CIA also requires that Novartis's compliance policies "address . . . compensation (including through salaries, bonuses, and contests) for . . . sales representatives" and be "designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Novartis' Government Reimbursed Products . . . " *Id.* at (3)(q).

C. Drugs In Novartis's Cardiovascular Division

57. At all times relevant to the complaint, Novartis sold the drugs Lotrel, Diovan, Diovan HCT, Tekturna, Tekturna HCT, Exforge, Exforge HCT, Valturna, Tekamlo, and Starlix as part of its cardiovascular ("CV") division.

58. At all times relevant to the complaint, Novartis sold these drugs through its network of sales representatives who called on health care professionals throughout the United States. The drugs in Novartis's CV division were promoted together by sales representatives in various combinations. For example, a sales representative might be assigned to promote Lotrel and Diovan, or Diovan, Tekturna, and Valturna to particular doctors.

59. With the exception of Starlix, each of the drugs was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of hypertension.

60. Starlix was approved by the FDA in October 2000 for the treatment of diabetes. Many of Novartis's CV drugs are closely related from a clinical perspective. For example, Valturna is a combination of Tekturna and Diovan, while Diovan HCT is a combination of Diovan and a diuretic.

D. Novartis Created Incentives for Sales Representatives to Use Speaker Programs as Kickbacks Without Sufficient Controls to Prevent Kickbacks from Occurring

61. From 2001 through at least 2011, Novartis conducted speaker programs as a key component of its promotional activities aimed at increasing sales of its drugs. According to Novartis's data, it spent over $65 million and conducted more than 38,000 speaker programs for Lotrel, Starlix and Valturna during the period from January 1, 2002 through November 2011. Of this $65 million, Novartis spent nearly $51 million for approximately 29,000 speaker programs on Lotrel between 2002 and 2007, when a generic competitor pharmaceutical product entered the market. For Starlix, Novartis spent nearly $4 million for approximately 3,200 speaker programs between 2002 and 2007, when a generic competitor pharmaceutical product entered the market. For Valturna, Novartis spent approximately $11 million for more than 6,500 programs from its approval by the FDA in 2009, until Novartis announced in April 2012 that it would withdraw Valturna from the market in July 2012.

62. At all times relevant to the Complaint, the vast majority of speakers for Novartis's speaker programs were nominated by sales representatives, who picked doctors from among those they called on to promote Novartis drugs.

63. A much smaller number of speakers, usually prominent doctors known as "key opinion leaders" ("KOLs"), were chosen by the drug's "brand team," an interdisciplinary group of marketing, sales and scientific specialists who were in charge of the overall management of each brand.

64. Sales representatives were compensated in part based on the number of prescriptions written by doctors on their call lists. This created incentives for sales

representatives to use speaker programs as a vehicle to pay kickbacks to doctors to increase their compensation.

65. Novartis used these speaker programs as remuneration to induce health care professionals to prescribe Novartis's drugs.

66. Speakers were paid each time that they spoke. Their compensation for each program, known as an "honorarium," was based on such factors as whether the speaker was certified in a specialty, was on the faculty of a teaching hospital, or had any publications or leadership roles in a medical association. However, although these factors affected the level of the honorarium a speaker was paid for each program, a doctor did not have to have any of these qualifications to be chosen as a speaker for Novartis.

67. Speakers were paid an average of between $750 and $1500 for each program depending on the leveling factors, with some speakers earning as much as $3000 per program. In addition to choosing the speakers, sales representatives also selected the attendees at speaker programs and were responsible for inviting them to the programs. As in the case of speakers, sales representatives generally chose attendees from the doctors on their call lists.

68. Some speakers were also paid honoraria for attending training events on the drugs about which they were also paid to speak. Speakers were paid up to $3,500 for each training event.

69. At all times relevant to the complaint, sales representatives selected the speaker, the topic of the program, and the date for the program. Sales representatives also selected the venues for speaker programs.

70. At all times relevant to the complaint, sales representatives scheduled programs for speakers in a speaker program computer database. From 2007 on, Novartis's speaker

program database was maintained by a vendor, Advanced Health Media ("AHM"), on Novartis's behalf.

71. At all times relevant to the Complaint, Novartis placed no limit on the number of programs a doctor could attend or how often a doctor could attend the same program. There was no system control to prevent a sales representative from repeatedly selecting the same doctors on his call list as attendees at speaker programs on exactly the same topics. Nor was there any system control that prevented a sales representative from arranging for the same doctors to take turns speaking and attending each other's programs repeatedly.

72. Novartis's E&C Policies require that a speaker program "have at least three Healthcare Professionals in attendance," although an event can "continue if, despite a good faith effort" fewer than three doctors attend. Novartis's E&C Policies note that sales representatives "should plan on inviting enough participants to ensure that the minimum requirement is met." Sales representatives were required to cancel a program if fewer than three attendees were confirmed prior to a program occurring.

73. In practice, many programs took place with less than three health care professionals in attendance. Moreover, many programs took place with no one in attendance except members of the speaker's own medical practice.

74. The vast majority of Novartis speaker programs run by the sales force were held in restaurants. At all times relevant to the complaint, Novartis sales representatives were required to choose a restaurant that complied with Novartis's E&C Policies on "modest meals." Starting in 2006, Novartis's policy defined modest meals based on locality, with caps of up to $100-125 per person in major cities such as New York and Los Angeles and $80-100 in other U.S. locations. The policy noted that "[m]ost business meals are expected to cost substantially

less than th[ose] amounts." (Emphasis in original.). In 2010, Novartis changed its policies to make the cap $125 per person nationwide.

75. In practice these limits could be - and were - avoided through attributing amounts over those caps to what Novartis termed an "unmet minimum," which was the difference between a restaurant's minimum spend for an event and the per person charge for the event. For example, if a restaurant had a minimum charge of $2,000 for an event, but only four people attended it, a sales representative could attribute $1,500 of the costs of the program, the amount exceeding the $125 per capita cost for four people, to the "unmet minimum" for the program. This practice, among others, permitted Novartis to spend lavishly on food and alcohol well beyond the purported "modest meal" caps in its written policies.

76. Novartis does not require that a restaurant have a private room to be an acceptable venue for a speaker program. Nor does Novartis require that the restaurant have a quiet atmosphere.

77. In addition, although Novartis's E&C Policies provide that only "modest" restaurants are acceptable venues for speaker programs, Novartis does not prohibit holding programs at restaurants that are high-end for the particular community in which they are located.

78. Novartis had few checks on whether sales representatives reported truthfully on who attended speaker programs they hosted. In many cases, Novartis did not even require signatures on attendance sheets at speaker events.

79. In addition, it was the sales representatives who set up and attended the events who were responsible for reviewing the accuracy of the receipts at venues where speaker programs took place.

80. Sales representatives' supervisors were made aware of each speaker program a sales representative hosted, the attendees who were purportedly present, and other details regarding the program. First line supervisors, called District Managers, and second-line supervisors, called Regional Managers, had access to the speaker program database and received reports regarding speaker programs.

81. In addition, Novartis's management was sent data regarding speaker programs. AHM provided Novartis with monthly reports regarding speaker programs.

E. Many Thousands of Novartis Speaker Programs Lacked Any Legitimate Purpose

82. Novartis's speaker program data shows that its programs were essentially lavish meals and entertainment with a veneer of education applied in an attempt to avoid the law and the CIA. From 2002 through at least 2011, doctors practicing in New York State and around the country spoke repeatedly to the same attendees on exactly the same topics. The doctors in these clusters took turns in the roles of speaker and attendee, with doctors repeatedly attending programs regarding the very same topics they had spoken about. Few or no slides were shown at many of these programs.

83. At each of these events, Novartis paid the speaker an honorarium between $500 and $3,500, and Novartis paid the tab at the locale or restaurant at which the dinner took place.

84. As an example, an internist in Brooklyn, New York, Dr. S.M., was the speaker at the same program on Valturna, a presentation entitled "Blood Pressure Efficacy with More Comprehensive RAAS Inhibition Versus an ARB," ten times from July 2010 to October 2011, with the same three doctors present at nine of the events. Likewise, Dr. S.M. and several of the other doctors who attended her Valturna events also took turns speaking to each other repeatedly

on a Lotrel topic, "Aggressive Strategies for Lowering BP in At-Risk Patients," in 2007. A Novartis sales representative was present at each of these events, and five of the Valturna events were hosted by the same sales representative.

85. As another example, a doctor in the Bronx, New York, Dr. B.A., spoke on the same Valturna topic, "Blood Pressure Efficacy With More Comprehensive RAAS Inhibition Versus an ARB," four times from November 2010 to September 2011, with one doctor attending all four times and two doctors attending three times. Dr. B.A. also attended that same program three times between April 2010 and September 2011 with many of the same doctors to whom he also gave that program. At many of the programs involving this cluster of doctors, no slide presentation was shown to the attendees.

F. Many Novartis Speaker Programs Were Merely Social Events at Which Novartis Wined and Dined or Otherwise Entertained the Physicians

86. Many Novartis speaker programs were merely expensive social events or dinners for the doctors and Novartis sales representatives, who were often friends with each other.

87. Novartis speaker programs were held at high-end restaurants or in circumstances or at locations that were not conducive to a legitimate educational event.

88. In fact, many Novartis speaker programs did not take place in a private room, making it difficult or impossible to hear the speaker or to show slides. When speaker programs occurred in the public space of a restaurant it was common practice not to show the slides.

89. For example, Novartis paid Dr. B.A. $500.00 to speak at Nobu, a famously high-end restaurant in New York City in May 2006 at a dinner attended only by himself, two of his physician friends, one of whom brought his girlfriend (who was not a health care professional)

and a Novartis sales representative. The dinner did not occur in a private room and no slides were presented.

90. As another example, in October 2005, Novartis paid a total of $1,428.86 -- or $285.77 per physician -- for a dinner for five physicians at the Mandarin Oriental Hotel in New York City.

91. Aside from not presenting the slide decks, many of the doctors who participated in Novartis speaker programs did nothing but socialize at the events. Often the only people who would come to a doctor's programs were people who knew the doctor. Novartis sales representatives understood the situation and would frequently ask speakers whom they should invite. The doctors who were willing to attend programs were often friends with each other who socialized outside the context of speaker programs as well.

92. The conversation at these dinners was generally not about the drug that purportedly was the subject of the speaker program. Doctors attended the programs to have dinner together, often at high-end restaurants, and to network with colleagues. They also attended each other's programs to ensure that they would all continue to be paid as Novartis speakers. The doctors knew that if they did not attend each other's events the programs could not take place and none of them would continue to get paid by Novartis.

G. Novartis Made Payments to Doctors for Speaker Programs That Did Not Occur or Were Not Attended by the Doctors Novartis Claimed Were Present

93. Some of the programs for which speakers were paid by Novartis either did not occur at all or did not have the attendees Novartis claims were present. Novartis created phony records regarding these speaker programs to make it appear that they were legitimate, educational programs with an appropriate number of attendees when they were not. For

example, the primary speaker in the Brooklyn cluster, Dr. S.M., was seeing patients at her office during the times when Novartis claimed that she was speaking about Lotrel on March 20, 2007 and April 17, 2007. She was paid an honorarium of $1,000 for "speaking" on each of those occasions, as well as "ground transportation" expenses, even though she was purportedly speaking at her own office. The purported attendees on these occasions were the exact same attendees that purportedly attended all of her events and whose events she in turn purportedly attended.

H. Novartis Paid Doctors Honoraria and Wined and Dined Them to Induce the Doctors to Write Prescriptions for Novartis Drugs

94. As Novartis found every year starting in 2004, speaker programs had a good return on investment. Novartis's Business Analysis Unit in 2004 reported that "[s]peaker programs for most brands exceed or approach break even after only 5 months and results are expected to improve through [the] year." The "best returns" were on doctors who wrote the highest numbers of prescriptions for Novartis drugs before participating in Novartis's speaker programs, known as "Tier 1" doctors, but "good returns are also possible for the lowest tier," according to Novartis's Business Analysis Unit, which was responsible for measuring the return on investment for speaker programs, among other promotional events.

95. Novartis intended that the more incentives doctors received in the form of meals, entertainment, and honoraria, the more the doctors would write prescriptions for Novartis drugs. In a "Meeting and Events Analysis" dated November 9, 2004, Novartis's Business Analysis Team noted that "Offering an honorarium is the top factor across all classes" of drugs driving the return on investment with respect to promotional programs. The Business Analysis Unit concluded in 2004 that if a doctor would not attend a "round table" program, which was cheaper

for Novartis because no one had to be paid an honorarium, then "invite [the doctor] to the most expensive speaker program."

96. In May 2006, Novartis found that speaker programs in 2005 for Lotrel had a return on investment of more than 1.39, meaning that for every dollar spent on the programs, Novartis made more than $1.39 in revenue on the increase in prescriptions written by these doctors as compared to a control group of doctors who did not participate in speaker programs. For the highest prescribers, the Tier 1 doctors, the return on investment was 2.52, meaning that these doctors wrote an additional $2.52 in prescriptions for Lotrel for every dollar Novartis spent on the programs in which they participated. For Tier 2 doctors, the return on investment was even higher - 2.77 - while for Tier 3 doctors, it was 1.57.

97. The honoraria that Novartis paid to the physician speakers at these sham speaker programs, as well as the free meals and entertainment that Novartis provided to the event attendees, were in fact remuneration paid to the physicians to induce them to prescribe Novartis drugs.

98. Novartis used its speaker programs to drive prescriptions and doctors knew it. Sales representatives chose doctors to be speakers based on high levels of prescriptions, which the doctors had to maintain or increase in order to continue to be invited to present programs.

99. An analysis of prescription-writing patterns for Novartis drugs by physicians who attended or were speakers at Novartis programs strongly indicates that the speaker programs in fact caused physicians to increase the number of prescriptions they wrote for Novartis drugs.

100. For example, Dr. B.A., a doctor in the Bronx cluster discussed above at Paragraph 85, substantially increased the number of Lotrel prescriptions that he wrote after he began receiving consistent honoraria payments from Novartis starting in March 2006. From January

2002 through February 2006, Dr. B.A. received one honoraria payment in connection with Lotrel ($550 for conducting one speaker program in November 2004), and he wrote an average of only 17.3 prescriptions per month. By contrast, from March 2006 through April 2007 — the period during which Dr. B.A. received additional honoraria payments in connection with Lotrel — he was paid $6,200 for conducting seven speaker programs, and his prescription writing for Lotrel skyrocketed to an average of 51.5 per month.

101. As another example, Dr. S.M., a doctor in the Brooklyn cluster discussed above at Paragraph 84, increased her prescription writing for Valturna as she received more honoraria for speaking about the drug. Dr. S.M. received her first honoraria payment for Valturna in October 2009 ($1,250 for attending one training event), but she did not write any prescriptions for Valturna until February 2010 when she received her second honoraria payment ($1,500 for conducting one speaker program). From February 2010 through June 2010, Dr. S.M. received only that one additional payment in February 2010, and she wrote an average of only 2.0 prescriptions per month. Dr. S.M. received a third honoraria payment in July 2010 ($1,500 for conducting another speaker program), and she wrote 4.9 prescriptions that month and 16.9 the next month. Thereafter, from September 2010 through November 2011, Dr. S.M. received honoraria payments of at least $1,500 in eight of those fifteen months (a total of $13,500 for conducting nine speaker programs). Over that period, Dr. S.M.'s prescription writing remained at an elevated level: she wrote an average of 14.8 prescriptions per month.

102. Similarly, an analysis of New York State Medicaid claims data strongly indicates that Novartis speaker programs caused physicians to increase the number of prescriptions they wrote to Medicaid recipients for Novartis drugs.

103. For example, Dr. N.S. attended or was a speaker at a total of 71 Novartis events on the topic of Lotrel beginning in October 2002, ranking him among the 20 physicians who spoke at or attended the most Lotrel events.

104. Dr. N.S. alternated speaking and attending events with the identical topic, "Modern Management of Hypertension, Rationale for Combination Therapy," during five events occurring in June and October 2004. After Novartis paid him an honorarium of $1,000.00 for being a speaker at one of these events on October 4, Dr. N.S. attended two of these events within one week on October 13 and October 19. Also present at all three of these events were Dr. N.S.'s nephew (who is a physician), and Dr. M.S. In fact, the same five doctors were present at both the October 4 and October 19 events. The only change in attendance between the October 4 event at which Dr. N.S. spoke and the October 19 event was the addition of a single doctor at the October 19 event, and this doctor had previously attended the October 13 event less than a week earlier.

105. Later, on January 19, 2007, a "roundtable discussion" dinner held at a restaurant in Westchester County at a cost to Novartis of $600.00 was attended only by Dr. N.S., Dr. N.S.'s brother and nephew (both of whom are physicians), Dr. N.A.S., and a Novartis sales representative.

106. Dr. N.S. wrote a total of 244 Lotrel prescriptions to Medicaid recipients in the two year period after he attended his first Lotrel event, for which Medicaid paid $17,010.76 in reimbursement.

107. By contrast, Dr. N.S. wrote only 145 Lotrel prescriptions to Medicaid recipients in the two year period before he attended his Lotrel first event.

108. In total, Dr. N.S. attended or spoke at over 100 Novartis events on the topics of Lotrel, Starlix and Valturna from October 2002 through September 2011.

109. Medicaid paid $118,150.70 in reimbursement for Lotrel, Starlix and Valturna prescribed by Dr. N.S. during the period October 2002 through September 2011.

110. Another physician, Dr. M.H., attended or was a speaker at a total of 69 Novartis events on the topic of Lotrel beginning in February 2003, ranking him among the 20 physicians who spoke at or attended the most Lotrel events.

111. In addition, during the period from September 2010 through October 2011, Dr. M.H. was part of the Bronx Cluster of doctors referenced above at Paragraph 85 who took turns speaking at and attending events on the same Valturna topic. Dr. M.H. was a speaker at two such events and attended a third event at which Dr. B.A. was the speaker.

112. Dr. M.H. wrote a total of 430 Lotrel prescriptions to Medicaid recipients in the two years after he attended his first Lotrel event, for which Medicaid paid $30,045.58 in reimbursement.

113. By contrast, Dr. M.H. wrote a total of only 358 Lotrel prescriptions to Medicaid recipients in the two years before he attended his first Lotrel event.

114. In addition, Dr. M.H. wrote a total of 86 prescriptions for Valturna to Medicaid recipients from the 3rd quarter of 2010 through the 3rd quarter of 2011, the same time period during which he was a speaker or attendee at the Valturna events referenced above. Medicaid paid $8,571.15 in reimbursement for these Valturna prescriptions. By contrast, Dr. M.H. wrote a total of 3 Valturna prescriptions to Medicaid recipients prior to this time period.

115. In total, Dr. M.H. attended or spoke at nearly 100 Novartis events on the topics of Lotrel and Valturna from February 2003 through November 2011.

116. Medicaid paid $74,411.15 in reimbursement for Lotrel and Valturna prescribed by Dr. M.H. from February 2003 through September 2011.

117. Another physician, Dr. E.C. attended or was a speaker at 36 separate Novartis events on the topic of Starlix beginning in November 2002, ranking him among the 20 physicians who spoke at or attended the most Starlix events.

118. Dr. E.C. wrote a total of 82 Starlix prescriptions to Medicaid recipients during the one year period after he attended his first Starlix event, for which Medicaid paid $7,956.31 in reimbursement.

119. By contrast, Dr. E.C. wrote only 26 Starlix prescriptions to Medicaid recipients during the one year period before he attended his first Starlix event.

120. In total, Dr. E.C. attended or spoke at over 100 Novartis events on the topics of Lotrel, Valturna and Starlix from November 2002 through November 2010.

121. Medicaid paid $37,144.21 in reimbursement for Lotrel, Starlix and Valturna prescribed by Dr. E.C. during the period November 2002 through April 2011.

122. On average, the twenty New York physicians who attended or were speakers at the largest number of Lotrel speaker events increased the number of Medicaid prescriptions they wrote for Lotrel by 23% in the two years after they attended their first event, as compared to the two years prior.

123. Similarly, on average, the twenty New York physicians who attended or were speakers at the largest number of Starlix speaker events increased the number of Medicaid prescriptions they wrote for Starlix by 30% in the one year period after they attended their first speaker event, as compared to the one year period prior.

124. Thus, Novartis's speaker events had the intended effect of inducing physicians who were speakers at or attended the events to write more prescriptions for Novartis drugs.

125. In addition to the incentives that the speaker programs provided to physicians, Novartis sales representatives had strong incentives to use speaker programs to reward doctors for writing prescriptions or to induce them to increase their number of prescriptions, because Novartis compensated its sales representatives in part based on how many prescriptions those doctors wrote.

I. Novartis's Compliance Program was Woefully Inadequate to Prevent Fraud With Respect to Its Speaker Programs

126. Even after Novartis entered into a CIA with the Office of lnspector General of the United States Department of Health and Human Services in September 2010, its compliance program included insufficient controls to prevent speaker programs from being used as a vehicle for kickbacks to doctors through the payment of honoraria or lavish dinners and entertainment. Novartis had no controls to prevent sales representatives from hosting programs in which the same doctors spoke repeatedly to the same attendees on exactly the same topic.

127. Nor did Novartis have sufficient controls to ensure that speaker programs were occurring as claimed by the sales representatives and recorded in Novartis's speaker program platform. Sales representatives recorded data regarding the attendees at each program in that platform. Considering that sales representatives could benefit financially by paying kickbacks to doctors on their call list, this system for ensuring that programs occurred as documented created incentives for abuse. Novartis often did not even require purported attendees at speaker events to sign the attendance sheets at the programs.

128. Novartis management was made aware of the inadequacies in its existing compliance programs and the numerous violations of it that occurred.

129. In fact, Novartis's board of directors was informed of significant compliance issues on March 19, 2009 at a presentation entitled "Representatives [sic] Interactions With Healthcare Professionals," given by the Executive Director of Ethics and Compliance and the Director of Regulatory Compliance. The presentation included the following findings regarding speaker programs:

- "Discrepancies existed between attendees physically present, attendees per Sign In Sheets and attendees per Event Alliance [the speaker program database] records";
- "Frequent utilization of venues not conducive to a private business meeting";
- "An insufficient number of HCPs (<3) in attendance at programs";
- "Excessive meal and alcohol costs at Field Managed Promotional Speaker Events . . . primarily due to a lack of responsibility for reviewing itemized meal receipts";
- "Lack of responsibility to monitor the speaker's performance in presenting the approved materials"; and
- "Inappropriate speaker conduct and non-compliance with policies."

130. Despite being aware of these issues, Novartis' response remained inadequate.

131. Moreover, Novartis knew or should have known that its speaker programs continued to be plagued with problems as a result of the monitoring it was required to conduct pursuant to the CIA.

132. A report from the Ethics and Compliance ("E&C") Department to Novartis' s Board of Directors on March 9, 2011, indicated that out of 22 speaker programs the E&C Department had monitored in the fourth quarter of 2010, the speaker did not present slides at three programs and at eight programs the monitor observed violations of the meal policy. These violations occurred even

though the monitor informed the sales representative hosting the program ahead of time that it would be audited.

J. In Addition to Lotrel, Valturna and Starlix, Novartis Conducted Sham Speaker Programs With Respect to Other Drugs

133. In addition to Lotrel, Valturna, and Starlix, during the period from January 2002 through at least November 2011, Novartis also promoted Diovan, Diovan HCT, Tekturna, Tekturna HCT, Tekamlo, Exforge, and Exforge HCT as part of its cardiovascular division. Although, as relevant to this Complaint, the September 2010 Settlement released claims related to speaker program fraud for the drugs Diovan, Tekturna, and Exforge through December 31, 2009, the settlement, by its terms, did not release claims for Tekamlo or for any of the HCT forms of these drugs. Numerous speaker programs occurred with respect to Tekamlo and the HCT forms of Diovan, Tekturna and Exforge throughout the time period relevant to this complaint.

134. Moreover, Novartis continued to conduct speaker programs on Diovan, Tekturna, and Exforge after December 31, 2009, through at least the end of 2011.

K. Novartis Caused Thousands of False Claims to be Submitted To and Paid By The New York State Medicaid Program

135. Novartis caused many thousands of prescriptions to be written as a result of speaker programs that were kickbacks to doctors. Novartis paid at least 4,595 New York physicians kickbacks in the form of honoraria and/or meals and entertainment in conjunction with speaker programs during the period from January 2002 through November 2011. The New York State Medicaid Program in turn paid over $34,500,000.00 for prescriptions written by these physicians for Lotrel, Starlix and Valturna alone during this same time period.

136. Attached as Exhibit A to this Complaint is a spreadsheet listing claims reimbursed by Medicaid for those Novartis drugs referenced in this Complaint[2] which were prescribed by five of these physicians, each of whom are discussed *supra*: Dr. B.A., Dr. S.M., Dr. N.S., Dr. M.H., and Dr. E.C. Each of these physicians wrote prescriptions for Novartis drugs which were induced by honoraria and exorbitant meals and entertainment provided by Novartis. The claims listed on Exhibit A are limited to claims submitted after these physicians began attending Novartis events.

137. As discussed, *supra*, in order to submit claims to Medicaid, physicians are required to sign a Certification Statement attesting that the care, services or supplies for which claims to Medicaid are submitted were furnished "in accordance with applicable federal and state laws and regulations," including but not limited to the Federal and New York Anti-Kickback Statutes.

138. In addition, in order to dispense and submit claims to Medicaid for prescription medications, pharmacies are required to sign the same Certification Statement referenced in the preceding paragraph, attesting that the care, services or supplies for which claims to Medicaid are submitted were furnished "in accordance with applicable federal and state laws and regulations," including but not limited to the Federal and New York Anti-Kickback Statutes.

139. Attached as Exhibit B to this Complaint are copies of Certification Statements for the years 2002 through 2011 which were signed by Dr. B.A., Dr. S.M., Dr. N.S., Dr. M.H., and Dr. E.C.

[2] The drugs are: Lotrel, Starlix, Valturna, Diovan, Diovan HCT, Tekturna, Tekturna HCT, Tekamlo, Exforge, and Exforge HCT.

140. Attached as Exhibit C to this Complaint are copies of Certification Statements for the years 2002 through 2011 for a sample of the pharmacies which dispensed the Novartis medications listed on Exhibit A.

141. The Certification Statements are representations of compliance with a material condition of payment, namely that the Novartis drugs for which claims for payment were made to Medicaid were provided in accordance with all applicable Federal and State laws regarding the provision of health care services, including the Federal and New York Anti-Kickback Statutes. Kickbacks that Novartis paid to physicians as alleged herein render those certifications false.

142. In addition, the Certification Statements are representations of compliance with another material condition of payment, namely the prohibition against "offering or paying either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program." 18 N.Y.C.R.R. § 515.2(b). Kickbacks that Novartis paid to physicians as alleged herein render those certifications false.

143. Claims for payment for Novartis drugs prescribed by physicians who received kickbacks from Novartis as alleged herein expressly and impliedly misrepresent compliance with multiple material conditions of payment of the New York State Medicaid Program.

144. Through kickbacks to physicians in the form of honoraria and meals and entertainment as described in this Complaint, Novartis caused the submission of false claims to the New York State Medicaid Program, including, but not limited to, the claims listed on Exhibit A to this Complaint.

145. By providing remuneration to physicians, Novartis intended to induce those physicians to prescribe certain of Novartis's drugs. It was reasonably foreseeable that some of those prescriptions would be for New York State Medicaid beneficiaries and that claims based on those prescriptions would be submitted to the New York State Medicaid program. Thousands of such claims were, in fact, submitted to and reimbursed by the New York State Medicaid program, including, but not limited to, the claims listed on Exhibit A to this Complaint.

146. Novartis is therefore liable to the State of New York for damages based upon payment of the claims for Novartis prescription drugs listed on Exhibit A to this Complaint, to the extent that such liability was not previously released pursuant to the September 2010 Settlement.

147. In addition, Novartis is liable to the State of New York for damages based upon payment of all other claims for Novartis prescription drugs arising from kickbacks in the form of honoraria and meals and entertainment as described in this Complaint during the period January 2002 through November 2011, to the extent that such liability was not previously released pursuant to the September 2010 Settlement.

FIRST CLAIM FOR RELIEF

(New York State False Claims Act: Presentation of False Claims in Connection with Violation of Anti-Kickback Laws)
(N.Y. State Fin. Law § 189(1)(a))

148. Plaintiff repeats and realleges each of the proceeding paragraphs as if fully set forth herein.

149. As a result of Novartis's kickbacks to induce doctors to prescribe Novartis drugs in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2) the New York Anti-Kickback Statute, New York Social Services Law § 366-d(2), and the laws, rules and

regulations of the New York State Medicaid Program, false and fraudulent claims for payment based on these prescriptions were made to the State of New York. Accordingly, Novartis knowingly caused to be presented false or fraudulent claims for payment or approval in violation of N.Y. State Fin. Law § 189(1)(a).

150. By reason of the false or fraudulent claims, the State of New York has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of $6,000 to $12,000 for each violation.

SECOND CLAIM FOR RELIEF

(New York State False Claims Act: Making or Using False Records or Statements to Cause Claims to be Paid in Connection with Violation of Anti-Kickback Laws)
(N.Y. State Fin. Law § 189(1)(b))

151. Plaintiff repeats and realleges each of the proceeding paragraphs as if fully set forth herein.

152. As a result of Novartis's kickbacks to induce doctors to prescribe Novartis drugs in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2) the New York Anti-Kickback Statute, New York Social Services Law § 366-d(2), and the laws, rules and regulations of the New York State Medicaid Program, Novartis knowingly caused doctors and pharmacies to make false records or statements that were material to false or fraudulent claims for payment submitted to the State of New York, in violation of N.Y. State Fin. Law § 189(1)(b). The false records or statements were the doctors' and pharmacies' false certifications and representations that the services were provided in compliance with all applicable Federal and State laws and regulations, including but not limited to the Federal and New York Anti-Kickback Statutes and the laws, rules and regulations of the New York State Medicaid Program.

153. By reason of the false records or statements, the State of New York has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of $6,000 to $12,000 for each violation.

THIRD CLAIM FOR RELIEF

(New York Social Services Law §145-b)

154. Plaintiff repeats and realleges each of the preceding paragraphs as if fully set forth herein.

155. As set forth above, Novartis knowingly, or acting in deliberate ignorance or in reckless disregard for the truth, caused to be presented to the State false or fraudulent claims for payment.

156. The State of New York paid such false or fraudulent claims because of the acts of Novartis.

157. By reason of Novartis' conduct, the State has been damaged in a substantial amount to be determined at trial.

158. By reason of the foregoing, Novartis is liable, pursuant to N.Y. Social Services Law §145-b, to the State for treble damages, penalties, and costs.

FOURTH CLAIM FOR RELIEF

(New York Executive Law § 63(12): Repeated and Persistent Fraud)

159. Plaintiff repeats and realleges each of the preceding paragraphs as if fully set forth herein.

160. N.Y. Executive Law § 63(12) makes "repeated fraudulent . . . acts of . . . persistent fraud . . . in the carrying on, conducting or transaction of business actionable by the Attorney General."

161. By engaging in the acts and practices described above, Novartis has engaged in repeated fraudulent acts or persistent fraud in violation of N.Y. Executive Law § 63(12).

162. By reason of the foregoing, Novartis is liable to the State for damages, in an amount to be determined at trial.

FIFTH CLAIM FOR RELIEF

(New York Executive Law § 63-c: Overpayment of Public Funds)

163. Plaintiff repeats and realleges each of the preceding paragraphs as if fully set forth herein.

164. The acts and practices of Novartis complained of herein constitute a misappropriation of public property, in violation of N.Y. Executive Law § 63-c. By reason of the foregoing, the State is entitled to restitution from Novartis in an amount yet to be determined, plus the maximum amount of interest available under law.

SIXTH CLAIM FOR RELIEF

(Unjust Enrichment)

165. Plaintiff repeats and realleges each of the preceding paragraphs as if fully set forth herein.

166. This is a claim for the recovery of monies by which Novartis has been unjustly enriched.

167. By directly or indirectly obtaining Government funds to which it was not entitled, Novartis has been unjustly enriched, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State.

WHEREFORE, the State demands and prays that judgment be entered in its favor against Novartis as follows:

1. On the First and Second Claims for Relief under the New York State False Claims Act, for the amount of the State's damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

2. On the Third Claim for Relief under New York Social Services Law § 145-b, for the amount of the State's damages, trebled, plus interest at the highest legal rate.

3. On the Fourth Claim for Relief under New York Executive Law § 63(12), for restitution to the State based on Novartis' repeated or persistent fraudulent and illegal practices, for the economic injuries suffered by the State.

4. On the Fifth and Sixth Claims for Relief, for the damages sustained and/or amounts by which Novartis was unjustly enriched or by which Novartis retained illegally obtained monies, plus interest, costs, and expenses, and all such further relief as may be just and proper.

Dated: August 26, 2013
New York, New York

Respectfully submitted,

ERIC T. SCHNEIDERMAN
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By: _____

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